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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/584,651	04/17/2007	Borut Furlan	33578US-PCT	5011

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CORPORATE INTELLECTUAL PROPERTY
ONE HEALTH PLAZA 104/3
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EXAMINER	
KATAKAM, SUDHAKAR	
ART UNIT	PAPER NUMBER
1621	
MAIL DATE	DELIVERY MODE
01/29/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/584,651	FURLAN ET AL.	
	Examiner	Art Unit	
	Sudhakar Katakam	1621	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 December 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *2-10* is/are pending in the application.

4a) Of the above claim(s) *5-10* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *2-4* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of the application

1. Receipt of Applicant's remarks and arguments filed on 9th Dec 2008 is acknowledged.

2. Applicants' arguments for the 103(a) rejection are not found persuasive and therefore, the previous rejection (see below) made on 9th July 2008 has been maintained.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

5. Claims 2-4 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Hoorn et al** (US 6,835,853).

The instant claims are drawn to a reaction mixture comprising tamsulosin hydrochloride containing less than 0.1% of overalkylated products.

Hoorn et al teach tamsulosin hydrochloride at more than a 99.9% purity.

Hoorn et al is deficient in that it does not explicitly state the content of the possible impurities.

However, it is the position of the examiner that there is no unexpected result in the production of tamsulosin hydrochloride with less than 0.1% of overalkylated products, since the prior art teaches the same end product and starting materials. Thus it is expected that the impurities would be similar. Because the patent office is not equipped with the ability to make the determination of the amount of overalkylated products remaining in the tamsulosin hydrochloride in the prior art, the burden is shifted to the applicant to establish an unexpected result and make a comparison with the cited prior art.

Therefore, it would be prima facie obvious to one of ordinary skill in the art at the time of the invention, to isolate tamsulosin hydrochloride containing less than 0.1% of overalkylated products. One of ordinary skill in the art would be motivated isolate pure tamsulosin hydrochloride, with the reasonable expectation that the compound would show increased potency in the treatment of cardiac insufficiencies and improved pharmacological activities. Absent any showing of unusual and/or unexpected results over Applicant's particular tamsulosin hydrochloride, the art obtains the same effect on the purity of tamsulosin hydrochloride in the prior art. Furthermore, the limitations in

some of the dependent claims, not expressly taught in the art, are also deemed to be obvious. One of ordinary skill in the art would be motivated to tweak and optimize these parameters to arrive at the instantly claimed invention. The expected result would be the efficient production of tamsulosin hydrochloride for the pharmaceutical industry.

6. Claims 2-4 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Fujikura et al** (AT 397 960).

Fujikura et al teach tamsulosin hydrochloride with an approximate 99.95 purity (calculated from the difference in elemental analysis between "calculated" and "found" on page 9, lines 19-25).

Fujikura et al is deficient in that it does not explicitly state the content of the possible impurities.

However, it is the position of the examiner that there is no unexpected result in the production of tamsulosin hydrochloride with less than 0.1% of overalkylated products, since the prior art teaches the same end product and starting materials (page 5, lines 1-45). Thus it is expected that the impurities would be similar. Because the patent office is not equipped with the ability to make the determination of the amount of overalkylated products remaining in the tamsulosin hydrochloride in the prior art, the burden is shifted to the applicant to establish an unexpected result and make a comparison with the cited prior art.

Therefore, it would be prima facie obvious to one of ordinary skill in the art at the time of the invention, to isolate tamsulosin hydrochloride containing less than 0.1% of

overalkylated products. One of ordinary skill in the art would be motivated isolate pure tamsulosin hydrochloride, with the reasonable expectation that the compound would show increased potency in the treatment of cardiac insufficiencies and improved pharmacological activities. Absent any showing of unusual and/or unexpected results over Applicant's particular tamsulosin hydrochloride, the art obtains the same effect on the purity of tamsulosin hydrochloride in the prior art. Furthermore, the limitations in some of the dependent claims, not expressly taught in the art, are also deemed to be obvious. One of ordinary skill in the art would be motivated to tweak and optimize these parameters to arrive at the instantly claimed invention. The expected result would be the efficient production of tamsulosin hydrochloride for the pharmaceutical industry.

Response to Arguments

7. Applicant's arguments filed on 9th Dec 2008 have been fully considered but they are not persuasive.

The thrust of the applicants' arguments is that neither **Hoorn et al** nor **Fujikara et al** provide any motivation to minimize the concentration of these overalkylated products.

However, examiner asserts that applicants are claiming "a reaction mixture comprising tamsulosin hydrochloride containing less than 0.1% of overalkylated products", not a process to minimize the concentration of overalkylated products.

Applicants also argue that the examiner has not made out a prima facie case of obviousness.

However, examiner asserts that obviousness can only be established by modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See In re Fine, 837 F.2d 1071,5 USPQ2d 1596 (Fed. Cir. 1988)and In re Jones, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, it is permissible for the examiner to rely on disclosures, which fairly teach embodiments of Applicant's invention. The claims require a reaction mixture comprising tamsulosin hydrochloride containing less than 0.1% of overalkylated products and it is reasonable for one of ordinary skill in the art to consider these elements being used in the references, which teaches tamsulosin hydrochloride at more than a 99.9% purity.

Applicants show how the cited references differ from the instant invention, but the obviousness test under 35 U.S.C. 103 is whether the invention would have been obvious in view of the prior art taken as a whole. **In re Metcalf et al. 157 U.S.P.Q. 423**.

The claims would have been obvious because, a person of ordinary skill has a good reason to pursue the known options within his or her technical grasp. If this leads to the anticipated success, it is likely the product, not of innovation, but of ordinary skill and common sense.

The claim would have been obvious because the design incentives or market forces provided a reason to make an adaptation, and the invention resulted from application of the prior knowledge in a predictable manner.

All the claimed elements were known in the prior art and one skilled person in the art could have combined the elements as claimed by known methods with no change in their respective functions, and the combination would have yielded predictable results to have yielded predictable results to one of ordinary skill in the art at the time of the invention.

Therefore, it would have been obvious to a person of ordinary skill in the art at the time of the invention was made, to use the teachings of the above cited references and to arrive at instant applicants composition or reaction mixture with a reasonable expectation of success.

8. THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136 (a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no even, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Conclusion

9. No Claim is allowed.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sudhakar Katakam whose telephone number is 571-272-9929. The examiner can normally be reached on M-F 8:30 AM - 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Daniel Sullivan can be reached on 571-272-079. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Sudhakar Katakam/
Examiner, Art Unit 1621

/SHAILENDRA - KUMAR/

Primary Examiner, Art Unit 1621